



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/375,605	08/17/1999	JAY M. SHORT	DIVER 1140-2	5334

7590

05/10/2002

GRAY CARY WARE & FREIDENRICH LLP
4365 EXECUTIVE DRIVE
SUITE 1100
SAN DIEGO, CA 92121-2189

EXAMINER

NASHED, NASHAAT T

ART UNIT	PAPER NUMBER
----------	--------------

1652

DATE MAILED: 05/10/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.



SERIAL NUMBER _____ FILING DATE _____ FIRST INVENTOR APPLICATION _____ ATTORNEY DOCKET NO. _____

BEST AVAILABLE COPY

EXAMINER	
ART UNIT	PAPER NUMBER
	16
DATE MAILED	

Below is a communication from the EXAMINER in charge of this application

COMMISSIONER OF PATENTS AND TRADEMARKS

ADVISORY ACTION

☐ THE PERIOD FOR RESPONSE:

- a) ☐ is extended to run _____ or continues to run _____ from the date of the final rejection
- b) ☐ expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

- ☒ Appellant's Brief is due in accordance with 37 CFR 1.192(a).
- ☒ Applicant's response to the final rejection, filed _____ has been considered with the following effect, but it is not deemed to place the application in condition for allowance:

1. ☒ The proposed amendments to the claim and /or specification will not be entered and the final rejection stands because:
- a. ☐ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.
 - b. ☒ They raise new issues that would require further consideration and/or search. (See Note).
 - c. ☐ They raise the issue of new matter. (See Note).
 - d. ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
 - e. ☐ They present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: _____

2. ☐ Newly proposed or amended claims _____ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.
3. ☒ Upon the filing an appeal, the proposed amendment ☐ will be entered ☒ will not be entered and the status of the claims will be as follows:

Claims allowed: None

Claims objected to: None

Claims rejected: 41-70

However;

- ☐ Applicant's response has overcome the following rejection(s): _____

4. ☒ The affidavit-exhibit request for reconsideration has been considered but does not overcome the rejection because See attached

5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficient reasons why it was not earlier presented.

- ☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.
- ☐ Other

Nashed
NASHAAT T. NASHED PH.D.
PRIMARY EXAMINER

The after-final amendment filed April 15, 2002 will not be entered because the amendment to claim 68 raises a new rejection under 35 U. S. C. § 112, second paragraph.

Claims 41-70 are under consideration in this Office action.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the phrase "mutagenesis in directed evolution" in claim 41, "at least 1 kb in size" in claim 44, "at least 5 kb in size" in claim 45, presumably "at least 10 kb in size" in claim 46, "at least 15 kb in size" in claim 47, "at least 20 kb in size" in claim 48, "at least 30 kb in size" in claim 49, "at least 35 kb in size" in claim 50, "at least 45 kb in size" in claim 51, "at least 60 kb in size" in claim 52, "at least 75 kb in size" in claim 53, "at least 150 kb in size" in claim 54, and "at least 200 kb in size" in claim 55 are not found in the original specification or the claims in the parent case, and therefore, it should be deleted.

Claim 46 is objected to because it is incomplete claim and does not end with a period. For examination purpose only, it is assumed that the applicant intended to insert the phrase "kb in size." after 10. Appropriate correction is required. The after-final amendment does not contains a proposed amendment to claim 46 which is alleged by applicants.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 41-70 are rejected under the judicially created doctrine of double patenting over claims 1-12 of U. S. Patent No. 5,939,250 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent for the reasons set forth in the prior Office action.

Claims 41-70 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 5,958,672 (672') in view of the prior art as exemplified by Arnold *et al.* (U. S. Patent 5,316,935) for the reasons set forth in the prior Office action.

Applicants have neither filed a terminal disclaimer or traverse the rejections stated above.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 41-70 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following are the reasons for the rejections:

- (a) Claim 41 is drawn to incomplete method because it is omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: (i) following step (a), isolating a DNA encoding a protein having a desired bioactivity; and (ii) need a step to isolate the wild-type protein of interest to compare the mutant protein to it.
- (b) The phrases "a desired bioactivity or biomolecule", "thru mutagenesis in directed evolution", and the two conditional clauses on lines 7 and 8 in claim 41 render the claim indefinite and confusing because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. The claim is drawn to a method of presumably obtaining a mutant protein having desired and improved activity relative to that of the wild-type.
- (c) Claim 68 contain the limitation "(c) enriching for a particular organisms of interest" renders the claim indefinite and confusing because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. The claim is dependent on claim 41 which limits the DNA to that isolated from an environmental sample. The DNA utilized in claim 41 is heterologous and one of ordinary skill in the art would not expect to know the various organisms which contributed to the DNA in the environmental

sample. Thus, one of ordinary skill in the art would not know which particular "organism or organisms" to enrich the sample with.

- (e) claims 41-67, 69 and 70 are included in this rejection because they are dependent on rejected claims and do not correct the deficiencies of the claim from which they depend.

The proposed amendment to the claims would not overcome the above rejections to claim 41 (a) and (b); and would introduce new issues regarding claim 68.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 41-70 are rejected under 35 U.S.C. § 102(e) as being anticipated by Thompson *et al.* (U. S. P. 5,824,485)

Claims 41-70 are rejected under 35 U.S.C. § 103 as being unpatentable over Thompson *et al.* in view of the state of the art as exemplified by the cited art, Stemmer *et al.* (Stemmer *et al.* Proc. Natl. Acad. Sci. U. S. A. 1994, 91, 10747-10751) and Arnold *et al.* for the reasons set forth in the prior Office action, paper number 12.

Claims 41-70 are rejected under 35 U.S.C. § 103 as being unpatentable over Thompson *et al.* in view of the state of the art as exemplified by the cited art, Stemmer *et al.* (Stemmer *et al.* Proc. Natl. Acad. Sci. U. S. A. 1994, 91, 10747-10751) and Arnold *et al.*

In response to the above rejections, Applicants argue that the claimed invention is not anticipate or obvious over Thompson *et al.* and any combination of references.

Applicants' arguments filed 4/15/02 have been fully considered but they are not deemed to be persuasive. The examiner disagree because applicants read the reference in a selected manner and disregard the particular teachings cited in the rejections. Thus, the claims remain rejected as indicated above.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is (703) 305-6586. The examiner can normally be reached Monday, Tuesday, Thursday, and Friday from 9:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (703) 308-3804. The fax phone numbers for this Group are (703) 305-3014 and (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Nashaat T. Nashed, Ph. D.
Primary Examiner